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PATENT

TECHNOLOGY CENTER R3700

Applicant: Whayne et al.

Serial No.: 09/507,613

Filing Date: 02/21/00

Title: Catheter Distal Assembly

With Pull Wires

Group Art Unit: 3763

Examiner: Rodriguez

I certify that on 2/14/03, which is the date I am signing this certificate, this correspondence and all attachments mentioned are being deposited in the United States Postal Service as first class in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231.

  
Craig A. Slavin

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents  
Washington, D.C. 20231

Attention: Board of Patent Appeals  
and Interferences

APPEAL BRIEF

I. REAL PARTY IN INTEREST

The real party in interest in the present appeal is EP Technologies, Inc., the assignee of the present application. EP Technologies, Inc. is a wholly owned subsidiary of Boston Scientific Corporation.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences which will directly affect, or be directly affected by, or have a bearing on, the Board's decision in the present appeal.

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### III. STATUS OF THE CLAIMS

Claims 10-37 are pending and are set forth in the Appendix (Exhibit 1). Claims 1-9 have been canceled. Claim 14 has been objected to. No claims have been allowed.

Claims 10-12, 15-23 and 27-37 have been rejected under 35 U.S.C. § 102 as being anticipated by U.S. Pat. No. 6,071,279 to Whayne ("the Whayne '279 patent"). Claims 13 and 24-26 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Whayne '279 patent and U.S. Pat. No. 5,439,006 to Brennen ("the Brennen '006 patent").

Applicant appeals the rejection of claims 10-13 and 15-37.

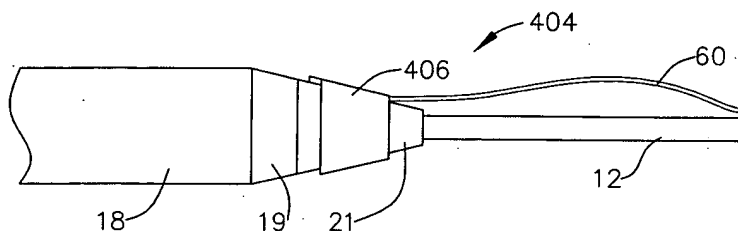
### IV. STATUS OF THE AMENDMENTS

No amendments were filed after the Final Rejection.

### V. SUMMARY OF THE INVENTIONS

Independent claim 10 is directed to a catheter assembly comprising a handle, an elongate catheter body and a control element. The handle includes a handle body and a **strain relief element**. The elongate catheter body defines a distal portion, a proximal portion associated with the handle, and a size and flexibility suitable for insertion into a human body. The **control element** defines a distal portion operably connected to the distal portion of the catheter body and a **proximal portion extending along the exterior surface of the catheter body**. The **proximal portion** of the control element is also secured to the strain relief element. Claims 11-21 depend from independent claim 10 and include, *inter alia*, all of the limitations of claim 10.

One example of a catheter assembly in accordance with the invention defined by independent claim 10 is illustrated in Figure 42, a formal version of which is reproduced below. The exemplary catheter assembly 404 includes a catheter 12, a handle 18 with a **strain relief element 21**, and a pull wire 60 with a **proximal portion that extends along the exterior** of the catheter 12. The **proximal portion** of the pull wire 60 is also secured to the handle's strain relief element 21 with an anchoring element 406.

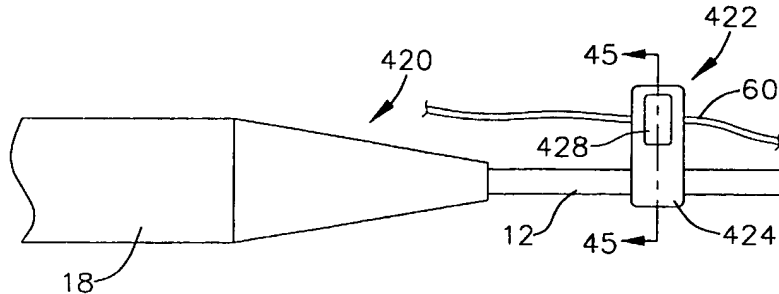


**Figure 42 of the Present Application**

Independent claim 22 is directed to a catheter assembly comprising a handle, an elongate catheter body, and a control element. The handle includes a handle body. The elongate catheter body defines a distal portion, a proximal portion associated with the handle, and a size and flexibility suitable for insertion into a human body. The control element defines a distal portion operably connected to the distal portion of the catheter body and a **proximal portion extending along the exterior surface of the catheter body**. The catheter assembly further comprises an **apparatus**, located in spaced relation to the handle body, that is **adapted to secure the proximal portion of the control element** in predetermined relation to the catheter body. Claims 23-37 depend from independent claim 22 and include, *inter alia*, all of the limitations of claim 22.

One example of a catheter assembly in accordance with the invention defined by independent claim 22 is illustrated in Figure 44, a formal version of which is reproduced on the following page. The exemplary catheter assembly 440 includes a catheter 12, a handle 18, and a pull wire 60 with a **proximal portion that extends along the exterior**

of the catheter 12. A gripping mechanism 422, which is located *in spaced relation to the handle 18*, holds the proximal portion of the pull wire 60 relative to the catheter 12.



**Figure 44 of the Present Application**

## **VI. ISSUES**

The present appeal presents the following two issues:

- (1) whether, in accordance with 35 U.S.C. § 102, claims 10-12, 15-23 and 27-37 have been properly rejected as being anticipated by the Whayne '279 patent; and
- (2) whether, in accordance with 35 U.S.C. § 103, claims 13 and 24-26 have been properly rejected as being unpatentable over the combined teachings of the Whayne '279 and Brennen '006 patents.

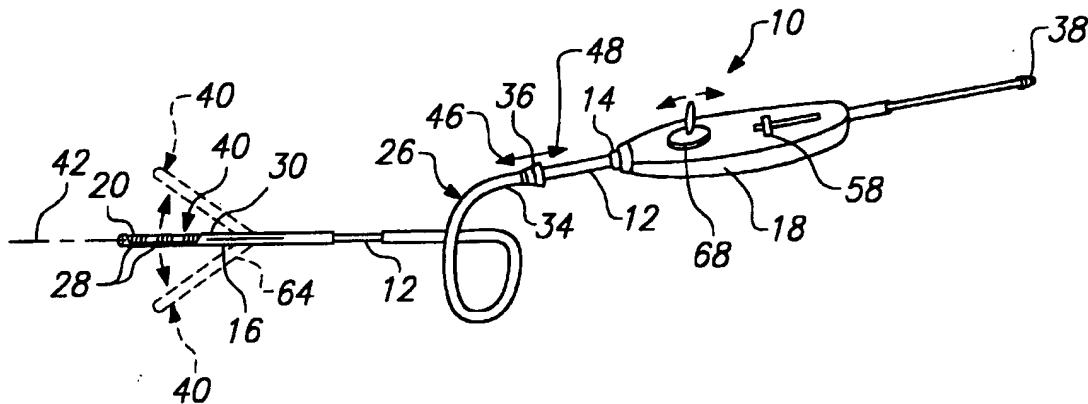
## **VII. GROUPING OF THE CLAIMS**

Applicant respectfully submits that claims 10-21 are patentably distinct from claims 22-37. Accordingly, claims 10-21 stand or fall together and claims 22-37 stand or fall together.

## VIII. ARGUMENTS

### A. The Cited References

The Whayne '279 patent discloses a variety of catheter probes. As illustrated in Figure 1, which is reproduced below, catheter 10 includes a catheter tube 12 with a proximal end 14, which is connected to a handle 18, and a distal end 16, which is connected to an electrode structure 20. The catheter 10 also includes structures that allow the physician to deflect the catheter tube distal end 16. As described in column 11, lines 45-57 and illustrated in Figure 2A of the Whayne '279 patent, the catheter tube distal end 16 is connected by a steering wire 66 to a steering mechanism 68 (i.e. a rotatable knob) on the handle 18. Rotation of the steering mechanism 68 causes the steering wire 66 to deflect the catheter tube distal end 16.

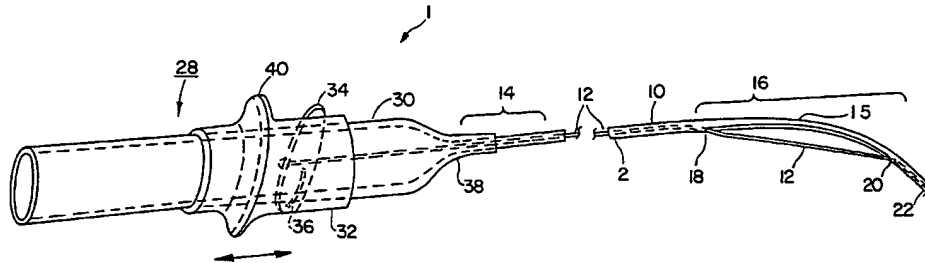


**Figure 1 of the Whayne '279 Patent**

The catheter 10 also includes a sheath 34 with a gripping surface 36. During use, the catheter tube 12 is located within the sheath 34 and is slidable relative to the sheath in the directions represented by arrows 46 and 48. [Column 9, lines 6-40.]

Referring to Figure 1, which is reproduced on the following page, the Brennen '006 patent discloses a steerable device including a tubular member 10, a pull wire 12

with a proximal section 14 and a distal section 16, and a handle 28. The handle 28 includes a pivotable lever that is used to pull the pull wire 12 in response to sliding movement of a slidable member 32. [Column 7, lines 16-49.]



**Figure 1 of the Brennen '006 Patent**

## **B. Claim Interpretation Issues Raised by the Final Office Action and Advisory Action**

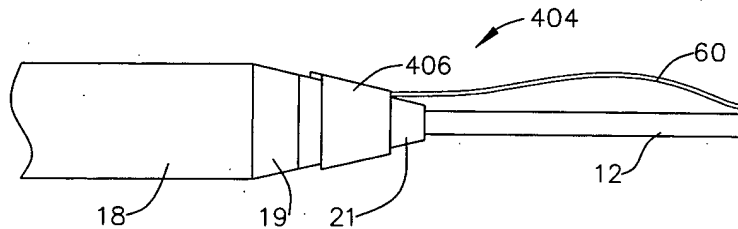
### **1. Strain Relief Element**

The Examiner has taken the position that the rotatable steering mechanism 68 disclosed in the Whayne '279 patent is a "strain relief element." [Final Office Action at page 2 and Advisory Action at page 4.] The Examiner's interpretation of the phrase "strain relief element" is unreasonable because (1) it is inconsistent with the specification of the present application and (2) it is inconsistent with the meaning given to the term "strain relief" in other catheter patents.

Claims in an application are to be given their broadest reasonable interpretation. This interpretation must be "consistent with the specification" and "consistent with the one that those skilled in the art would reach." *In re Cortright*, 49 USPQ2d 1464, 1467 (Fed. Cir. 1999). One way to determine the interpretation which one of skill in the art would ascribe to a particular term is to review analogous prior art references. *Vitronics Corp. v. Conceptronic, Inc.*, 39 USPQ2d 1573, 1578-79 (Fed. Cir. 1996) ("prior art can often help to demonstrate how a disputed term is used by those skilled in the art"). As such, "the PTO's interpretation of claim terms should not be so broad that it conflicts with the

meaning given to identical terms in other patents from analogous art.” *In re Cortright*, 49 USPQ2d at 1467.

With respect to the present specification, “strain relief elements” were notoriously well known devices at the time the present application was filed. “Strain relief elements” were, at the time the present application was filed, used to reduce the mechanical strain on the proximal portion of a catheter when the catheter is bent relative to a handle or other structure. For this reason, the present application did not go to great lengths to explain what a “strain relief element” is.<sup>1</sup> The specification identifies one example of a “strain relief element” as being represented by reference numeral 21 in Figures 41 and 42. [A formal version of Figure 42 is reproduced below.] Figures 41 and 42 present the strain relief element 21 as a structure that is associated with the handle 18 and the proximal end of the catheter tube 12.

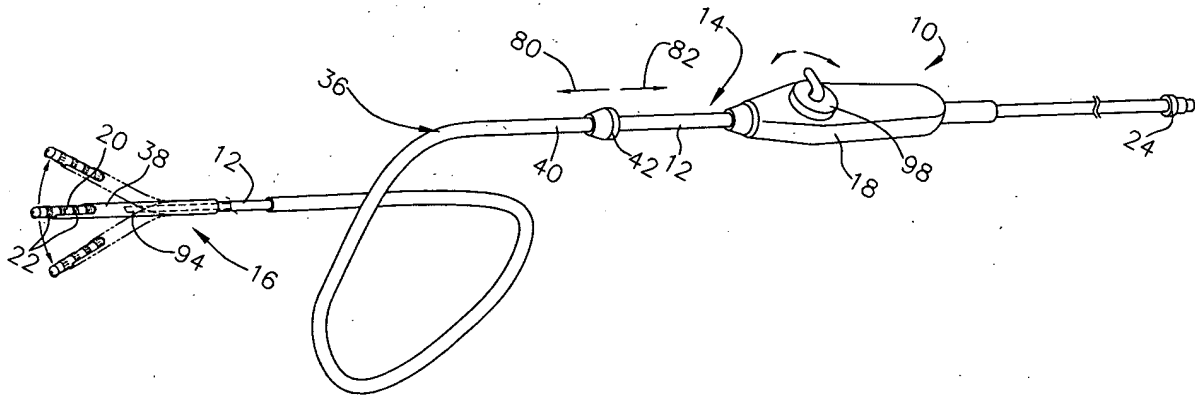


**Figure 42 of the Present Application**

The present application also discloses other catheter configurations, one of which includes steering wires and a rotatable steering mechanism that is used to pull the steering wires. Referring to Figure 1, a formal version of which is reproduced on the following page, the present application discloses a catheter 10 with a catheter tube 12 and a handle 18. The catheter 10 also includes structures that allow the physician to deflect the distal portion of the catheter tube 12. As described on page 16, lines 1-10, the distal region of the catheter tube 12 is connected by a steering wire 96 to a steering

<sup>1</sup> “[A] patent need not teach, and preferably omits, what is well known in the art.” *Hybritech Incorporated v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986).

mechanism 98 (i.e. a rotatable knob) on the handle 18. Rotation of the steering mechanism 98 causes the steering wire 96 to deflect the distal region of the catheter tube 12. In other words, the present application uses the phrase "steering mechanism" to refer to exactly the same structural element as the Whayne '279 patent, i.e. a rotatable device that is used to manipulate pull wires.



**Figure 1 of the Present Application**

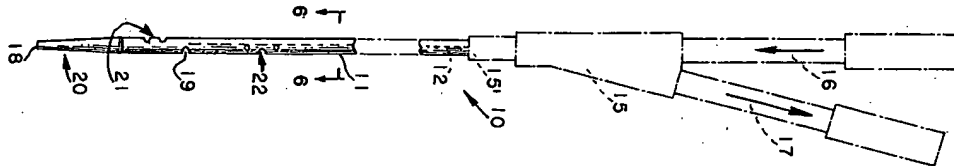
As illustrated above, the present specification makes it perfectly clear that a "strain relief element" and a rotatable steering mechanism are two entirely different things. The Examiner's interpretation of the phrase "strain relief element" is, therefore, inconsistent with the present specification and, for this reason alone, unreasonable.

The Examiner's interpretation of the phrase "strain relief element" also conflicts with the interpretation that those skilled in the art would reach. To that end, attached hereto are five analogous prior art references. Each of the references uses the phrase "strain relief" in the same manner as the present specification.

U.S. Patent No. 4,583,968 to Mahurkar ("the Mahurkar '968 patent") is attached hereto as Exhibit 2. Referring to Figure 1, which is reproduced on the following page, the Mahurkar '968 patent includes the following passage in column 3, lines 31-35:



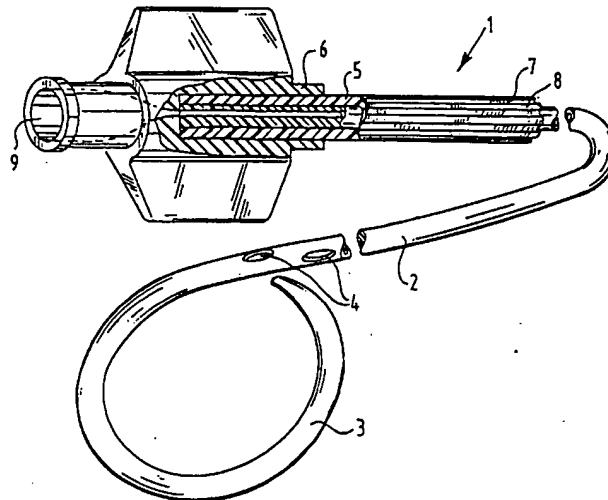
The branching connector 15 includes a coaxial sleeve 15' at the junction of the tube 11 and the connector 15. The sleeve 15' acts as a **strain relief** and also prevents kinking of the tube 11 at the junction. [Emphasis added.]



**Figure 1 of the Mahurkar '968 Patent (rotated)**

U.S. Patent No. 5,167,647 to Wijkamp ("the Wijkamp '647 patent") is attached hereto as Exhibit 3. Referring to Figure 1, which is reproduced below, the Wijkamp '647 patent includes the following passage in column 2, lines 43-50:

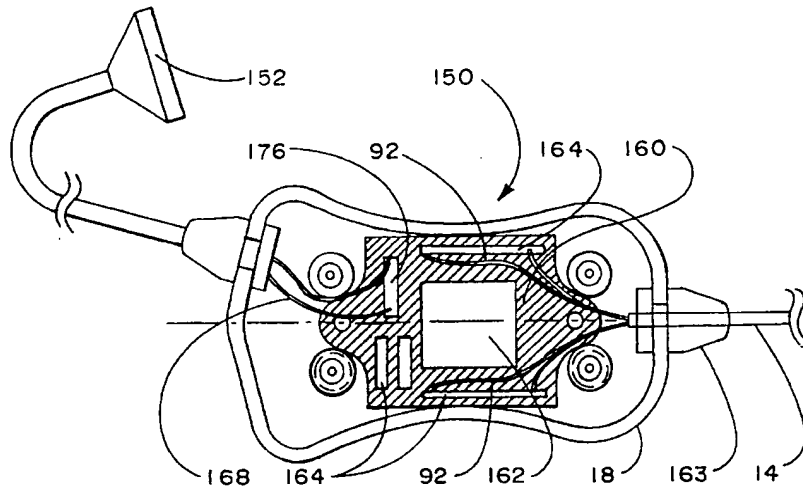
A **strain relief** tube 5 is pushed over the proximal end portion of the tubular body 2, while strain relief tube 5 is secured in an aperture in the coupling element 6. Strain relief member 5 serves to **reinforce the catheter** at that location. [Emphasis added.]



**Figure 1 of the Wijkamp '647 Patent**

U.S. Patent No. 5,499,981 to Kordis ("the Kordis '981 patent") is attached hereto as Exhibit 4. With reference to Figure 55, which is reproduced on the following page, the

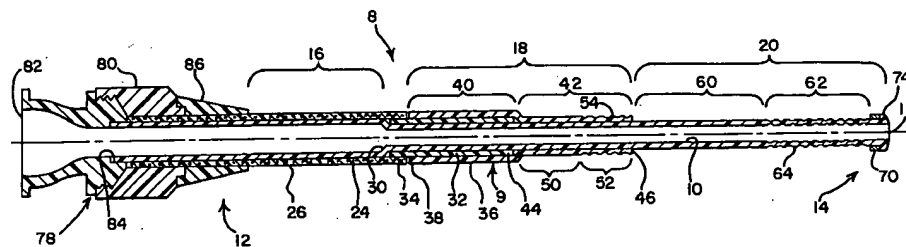
Kordis '981 patent states that "a **strain relief** 163 surrounds the junction of the proximal catheter tube 14 with the handle 18." [Column 15, lines 29-31, emphasis added.]



**Figure 55 of the Kordis '981 Patent**

U.S. Patent No. 5,507,995 to Schweich ("the Schweich '995 patent") is attached hereto as Exhibit 5. With reference to Figure 1, which is reproduced below, the Schweich '995 patent includes the following passage in column 6, lines 58-61:

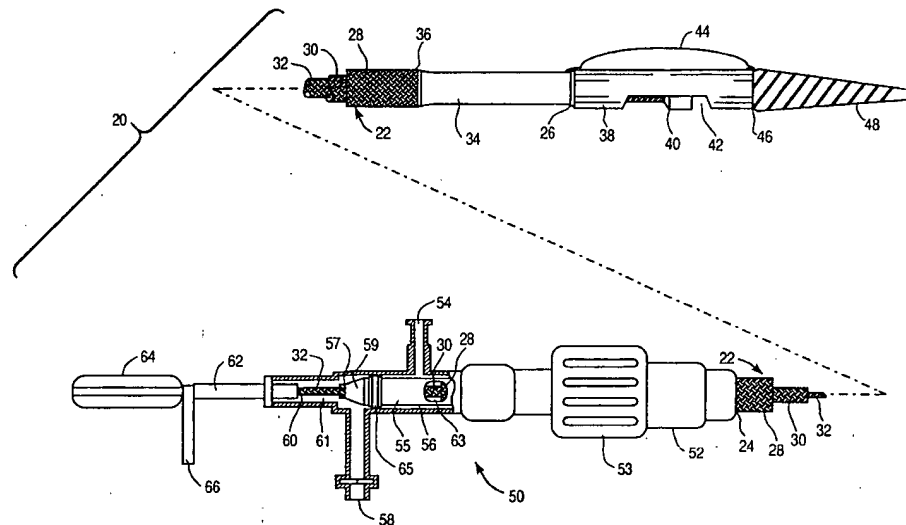
Located on a distal end of the manifold 78 and extending along the proximal end of the elongate shaft 9 is a **strain relief** 86. The strain relief 86 is made of a relatively flexible plastic material. [Emphasis added.]



**Figure 1 of the Schweich '995 Patent**

U.S. Patent No. 5,527,325 to Conley ("the Conley '325 patent") is attached hereto as Exhibit 6. Referring to Figure 1, which is reproduced on the following page, the Conley '325 patent states that the "proximal assembly 50 includes a distal **strain relief** 52 at the

point where catheter body 22 joins proximal assembly 50.” [Column 12, lines 52-54, emphasis added.]



**Figure 1 of the Conley '325 Patent**

As exemplified by five analogous patents, one of ordinary skill in the catheter art would understand the phrase “strain relief element” to be a reference to a device that is associated with a handle and that is used to reduce mechanical strains on the proximal portion of the catheter. The Examiner’s interpretation is, therefore, also in conflict the meaning given to the phrase “strain relief” in other patents from analogous art.

In view of the foregoing, applicant respectfully submits that the Examiner’s interpretation of the phrase “strain relief element” is unreasonable because it is inconsistent with the specification and is inconsistent with the one that those skilled in the art would reach. As illustrated in Figure 42 of the present application, and as discussed in five prior patents, a “strain relief element” is a device that reduces the mechanical strains on the proximal portion of a catheter as the catheter is bent relative to a handle or other structure. The Examiner’s hypothesis concerning strain on a steering wire notwithstanding, a “strain relief element” simply is not a rotatable steering knob.

## 2. Exterior Surface

Applicant respectfully submits that there is no reasonable interpretation of the phrase “**exterior surface** of the catheter body,” which is recited in independent claims 10 and 22, other than its ordinary English language meaning, i.e. the outside surface of the catheter body.

## 3. Proximal and Distal

The respective combinations of elements recited in independent claims 10 and 22 call for “a control element defining a **distal** portion operably connected to the **distal** portion of the catheter body and a **proximal** portion extending along the exterior surface of the catheter body.” The Examiner’s interpretation of claims 10 and 22 appears to indicate that the Examiner has either misinterpreted the terms “proximal” and “distal,” or has ignored them altogether.

Applicant respectfully submits that, in the context of the present specification and the catheter art generally, the term “proximal” is used to refer to the portion of a device that is close to the handle/physician and the term “distal” is used to refer to the portion of the device that is positioned at the target tissue region. For example, on page 9, lines 9-12, the present specification states that:

Fig. 1 shows a multiple electrode probe 10 having a flexible catheter tube 12 with a proximal end 14 and a distal end 16. The proximal end 14 has an attached handle 18. A multiple electrode structure 20 is attached to the distal end 16 of the catheter tube 12 (see Fig. 2A).

A formal version of Figure 1 of the present application is reproduce on page 8 above. With respect to the catheter art generally, and referring to Figure 1 (which is reproduced on page 5 above), the Whayne ‘279 patent includes the following passage in column 7, lines 48-52:

The probe 10 includes a flexible catheter tube 12 with a proximal end 14 and a distal end 16. The proximal end 14 has an attached handle 18. The multiple electrode structure 20 is attached to the distal end 16 of the catheter tube 14 (see FIG. 2A).

#### 4. CCPA and CAFC Decisions Cited By the Examiner

The Examiner cited a variety of decisions from the U.S. Court of Customs and Patent Appeals (“CCPA”) and U.S. Court of Appeals Federal Circuit (“CAFC”). [Advisory Action at pages 2-4.] The CCPA and CAFC decisions, which either actually support applicant’s arguments or have little to do with the issues at hand, are discussed below in the order in which they appeared in the Advisory Action.

Turning to the first cited decision, *In re Prater*, 162 USPQ 541, 550-551 (CCPA 1969), the portion of the decision referenced by the Examiner held, in the context of a rejection under 35 U.S.C. §112, that the applicant should not “have limitations of the specification read into the claim.” The present applicant has not argued that the limitations from the specification should be read into the claim. Rather, the present application uses the phrase “strain relief element” to describe a device that is notoriously well known in the catheter art. Applicant has simply argued that the Examiner’s interpretation of the phrase “strain relief element” should not be so broad that it conflicts with both the specification and the meaning ascribed to this phrase by those of skill in the art.

The court in *In re Morris*, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997), confirmed that the PTO is to give claims their broadest reasonable interpretation, as opposed to employing some of the post-issuance interpretation methods employed by the courts, and held that interpreting the term “integral” to cover more than “a unitary construction” was reasonable under the facts in that case. With respect to the present application, applicant has not argued that the claims should be afforded something other than their broadest reasonable interpretation. Instead, applicant has correctly argued that the broadest reasonable interpretation is one which is “consistent with the specification” and “consistent with the one that those skilled in the art would reach.” *In re Cortright*, 49 USPQ2d at 1467. Applicant has also provided an abundance of evidence as to what this interpretation should be, i.e. a device that is associated with a handle and used to reduce mechanical strains on the proximal portion of the catheter body. The Examiner, on the

other hand, has failed to point to a single prior art reference or other source of information which would support the proposition that, in the context of catheters, the phrase “strain relief element” corresponds to a rotatable steering mechanism.<sup>2</sup>

The next decision cited by the Examiner is *In re Cortright*, 49 USPQ2d 1464 (Fed. Cir. 1999). This decision is discussed in detail above. With respect to the portion of the *Cortright* decision pinpoint cited by the Examiner, the CAFC held that the PTO’s interpretation of the phrase “restore hair growth” was **too broad to be reasonable** in view of the **applicant’s disclosure** and the teachings of **three analogous patents**. 49 USPQ2d at 1468. Turning to the present application, the applicant’s disclosure clearly differentiates between a rotatable steering mechanism that is used to pull steering wires and “strain relief element”. Applicant has also cited **five analogous patents** which clearly indicate what is meant by the phrase “strain relief element” and that meaning is certainly not “rotatable steering knob.”

The Examiner’s appears to have cited *In re Zletz*, 13 USPQ2d 1320 (Fed. Cir. 1989) and *In re Vogel*, 164 USPQ 619 (CCPA 1970), in support of the proposition that “the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification.” [Advisory Action at page 3.] The Examiner has, however, failed to provide any support for the position that the plain meaning of “strain relief element” encompasses a rotatable steering mechanism as asserted in the Final Office Action. Again, to the contrary, applicant has cited five analogous patents which show that the plain meaning of the phrase “strain relief element” is something other than a rotatable steering mechanism.

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<sup>2</sup> Note that the court in *In re Morris* stated that “the fact that applicants can point to definitions or uses that conform to their interpretation does not make the PTO’s unreasonable **when the PTO can point to other sources that support its interpretation.**” *Id.* at 1029, emphasis added. Here, the Examiner has failed to do so.

The Examiner then cited a pair of means-plus-function cases, *In re Donaldson*, 29 USPQ2d 1845 (Fed. Cir. 1994) and the unpublished *In re Weiss*, 26 USPQ2d 1885 (Fed. Cir. 1993), which state that the specification must be consulted when interpreting claims that fall under the scope of 35 U.S.C. § 112, sixth paragraph. Given that the present application does not include means-plus-function claims, it is unclear why the Examiner cited the *Donaldson* and *Weiss* decisions.

Finally, in *In re Sneed*, 218 USPQ 385 (Fed. Cir. 1983), the court held that the applicant was not entitled to a claim interpretation which was in conflict with the prior art. That is certainly not the case here. Contrary to the situation in *Sneed*, applicant has argued that the phrase “strain relief element” should mean exactly what five different prior art references say it should mean, while the Examiner has failed to provide a single reference that would support the unreasonable interpretation set forth in the Final Office Action.

### C. Discussion Concerning Claims 10-13 and 15-21 and the Cited References

Independent claim 10 calls for a combination of elements comprising “a handle including a handle body and a **strain relief element**,” “an elongate catheter body” and “a control element defining a distal portion operably connected to the distal portion of the catheter body and a proximal portion extending along the **exterior surface** of the catheter body and **secured to the strain relief element**.”

#### 1. The Rejection of Claims 10-12 and 15-21 Under 35 U.S.C. § 102

Applicant respectfully submits that the Wayne ‘279 patent fails teach or suggest a number of elements in the combination defined by independent claim 10. For example, the Wayne ‘279 patent fails to teach or suggest the use of a “strain relief element.” The text of the Wayne ‘279 patent does not even include the word “strain” or the word “relief.” The Examiner has, nevertheless, taken the position that the rotatable steering element 68 in Figure 1 of the Wayne ‘279 patent corresponds to the claimed “strain

relief element.” Such an interpretation is unreasonable because it (1) is inconsistent with the specification and (2) is inconsistent with the interpretation that those skilled in the art would reach. [See the discussion in Section VIII-B-1 on pages 6-11 above.] For this reason alone, the rejection under 35 U.S.C. § 102 is improper and should be reversed.

The Whayne ‘279 patent also fails to teach or suggest “a control element defining ... a **proximal portion** extending along the **exterior** surface of the catheter body and secured to the strain relief element.” The Examiner has taken the position that the pull wire 152 (illustrated in Figures 21-24 and described in column 16, lines 16-18 of the Whayne ‘279 patent) corresponds to this aspect of the claimed combination. [Advisory Action at page 4.] This position is erroneous for a variety of reasons. For example, the pull wire 152 is not secured to the rotatable steering element 68, which is the device that corresponds to the “strain relief element” in the Examiner’s unreasonable interpretation of the claims.<sup>3</sup> Additionally, to the extent that the multiple electrode structure 144 illustrated in Figures 21-24 of the Whayne ‘279 patent is even part of the catheter tube 12, it is the **distal portion** of the pull wire 152 that extends along the exterior of the catheter tube 12.<sup>4</sup> The **proximal portion** of the pull wire is located **within the interior** of the catheter tube 12. The Whayne ‘279 patent specifically states that “the catheter tube 12 includes an interior lumen 156, which accommodates sliding passage of the pull wire 152.” [Column 16, lines 14-16.] Applicant respectfully submits that one of ordinary skill in the would certainly understand that the **interior** lumen 156 does not correspond to an “**exterior** surface” and, therefore, that the **proximal portion** of the Whayne pull wire 152 clearly does not extend along the **exterior** surface of the catheter tube 12.

Figures 18-20 of the Whayne ‘279 patent, which the Examiner raised in the Advisory Action, disclose a catheter which includes an electrode carrying sheath 130 that slides along a spline leg 124 in and out of the catheter tube 12. Referring to Figure 19,

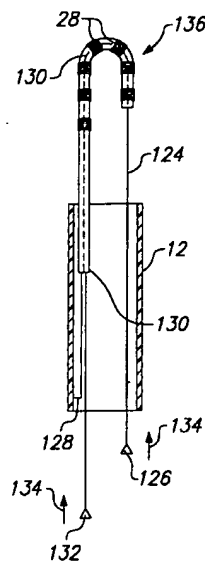
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<sup>3</sup> The Whayne ‘279 patent indicates that the pull wire 152 will instead be secured to a push pull control 166 that may be mounted on the handle 18. [Column 16, lines 16-18.]

<sup>4</sup> See the discussion concerning the terms “proximal” and “distal” in Section VIII-B-3 on page 12 above.



which is reproduced below, and column 15, lines 9-53, the spline leg 124 is secured to



**Figure 19 of the Whayne  
'279 Patent**

the interior of the catheter tube 12 at point 128, is bent into a loop, and then extends back through the interior of the catheter tube. The sheath 130 is pushed and pulled by an unnumbered spline leg (connected to control 132) which also extends through the interior of the catheter tube 12. Notwithstanding the fact that there is no mention of the use of a "strain relief element" or securing the splines thereto, the proximal portions of both splines are clearly located *within* the catheter tube 12 and **do not extend along the exterior surface** of the catheter tube.

The Advisory Action also referred to Figure 53 of the Whayne '279 patent. Here, it is at least arguable that the pull wire 334 is outside the catheter tube 12. In contrast to the claimed combinations, however, the pull wire 334 is not connected to the distal portion 16 of the catheter tube 12. [Note that reference numerals 12 and 16 are visible in Figures 52 and 54.] Instead, the pull wire 334 is connected to a branch structure 274 that slides through a lumen in the catheter tube 12. [Column 27, lines 2-9 and column 28, lines 1-15.] Moreover, there is nothing in the Whayne '279 patent that even remotely suggests that the pull wire 334 is secured to a "strain relief element."

As the Whayne '279 patent fails to teach or suggest each and every element of the combination recited in independent claim 10, applicant respectfully submits that claims 10-12 and 15-21 are patentable thereover and that the rejection under 35 U.S.C. § 102 is improper and must be reversed.

## 2. The Rejection of Claim 13 Under 35 U.S.C. § 103

The Brennen '006 patent, which was cited with respect to dependent claim 13, fails to remedy the deficiencies in the Whayne '279 patent described above with respect to independent claim 10. For example, the Brennen patent does not teach or suggest the use of a "strain relief element." The Examiner has taken the position that the pivotable lever 34, which is used to pull the pull wire 12, is a "strain relief element." As discussed in Section VIII-B-1 in the context of the Whayne rotatable steering element 68 (pages 6-11 above), such an interpretation is unreasonable because it is inconsistent with the specification and is inconsistent with the interpretation that those skilled in the art would reach.

The Brennen patent also fails to teach or suggest "a control element defining ... a **proximal portion** extending along the **exterior** surface of the catheter body and secured to the strain relief element." The **proximal section 14** of the Brennen pull wire 12 is clearly located **within the interior** of the tubular member 10. Applicant respectfully submits that one of ordinary skill in the would certainly understand that the **interior** of the Brennen tubular member 10, which is where the pull wire proximal section 14 is located, does not correspond to an "**exterior** surface" of a catheter.

As the Whayne '279 and Brennen '006 patents fail to teach or suggest the combination of elements recited in claim 13 (which by definition includes the combination of elements recited in independent claim 10), applicant respectfully submits that the rejection of claim 13 under 35 U.S.C. § 103 is improper and must be reversed.

### D. Discussion Concerning Claims 22-37 and the Cited References

Independent claim 22 calls for a combination of elements comprising "a handle," "an elongate catheter body," "a control element defining a distal portion operably connected to the distal portion of the catheter body and a **proximal portion** extending along the **exterior** surface of the catheter body" and "an apparatus, located in spaced

relation to the handle body, adapted to secure the proximal portion of the control element in predetermined relation to the catheter body.”

**1. Statement Under 37 C.F.R. § 1.192(c)(7)**

In accordance with the separate patentability requirements of 37 C.F.R. § 1.192(c)(7), applicant respectfully submits that claims 22-37 are patentably distinct from claims 10-13 and 15-21 because claims 22-37 are both novel and non-obvious over claims 10-13 and 15-21. With respect to novelty, independent claim 22 calls for “an apparatus, located in spaced relation to the handle body, adapted to secure the proximal portion of the control element in predetermined relation to the catheter body,” while claims 10-13 and 15-21 do not. Additionally, because the prior art does not suggest modifying the inventions defined by claims 10-13 and 15-21 such that they include the aforementioned “apparatus,” claims 22-37 are non-obvious over claims 10-13 and 15-21.

**2. The Rejection of Claims 22, 23 and 27-37 Under 35 U.S.C. § 102**

The Whayne ‘279 patent fails teach or suggest a number of elements in the combination defined by independent claim 22. For example, and as described in detail in Section VIII-C-1 (pages 15-17 above), the Whayne ‘279 patent fails to teach or suggest a combination of elements including “a control element defining a distal portion **operably connected** to the distal portion of the catheter body and a **proximal portion** extending along the **exterior surface** of the catheter body.” Instead, to the extent that the multiple electrode structure 144 illustrated in Figures 21-24 of the Whayne ‘279 patent is even part of the catheter tube 12, it is the **distal portion** of the pull wire 152 that extends along the exterior of the catheter tube 12. The **proximal portion** of the pull wire is located **within the interior** of the catheter tube 12. Similarly, the proximal portions of both of the splines are located within the catheter tube 12 in the embodiment illustrated

in Figures 18-20. In the embodiment illustrated in Figure 53, the pull wire 334 is not connected to the catheter tube 12.

The Examiner has also taken the position that element 36 in the Whayne '279 patent corresponds to the claimed "apparatus ... adapted to secure the proximal portion of the control element in predetermined relation to the catheter body." [Final Office Action at page 2.] Element 36 is merely the gripping surface for the sheath 26 through which the catheter tube 12 passes. The gripping surface 36 is not used to secure anything to the catheter tube 12. It is also noteworthy that the proximal portion of the pull wire 152 is located **within** the catheter tube 12 and is not even remotely associated with the gripping surface 36.

As the Whayne '279 patent fails to teach or suggest each and every element of the combination recited in independent claim 22, applicant respectfully submits that claims 22, 23 and 27-37 are patentable thereover and that the rejection under 35 U.S.C. § 102 is improper and should be reversed.

## 2. The Rejection of Claims 24-26 Under 35 U.S.C. § 103

Applicant respectfully submits that the Brennen '006 patent fails to remedy the deficiencies in the Whayne '279 patent described above with respect to independent claim 22. For example, the Brennen '006 patent does not teach or suggest the use of a control element with a **proximal** portion extending along the **exterior** surface of the catheter body. The **proximal section** 14 of the Brennen pull wire 12 is, instead, located **within** the tubular member 10. The Brennen '006 patent also fails to teach or suggest an apparatus, located in spaced relation to the handle 28, that secures the proximal portion of the pull wire 12 to the tubular member 10. To the contrary, the Brennen pull wire 12 is secured to the pivotable lever 34 on the handle 28.

As the Whayne '279 and Brennen '006 patents fail to teach or suggest the respective combinations of elements recited in claims 24-26 (which by definition include the combination of elements recited in independent claim 22), applicant respectfully

submits that the rejection of claims 24-26 under 35 U.S.C. § 103 is improper and must be reversed.

**D. The Present Application Claims Priority to an Application With the Same Priority Date as the Whayne '279 Patent**

The Whayne '279 patent, which has been applied to the claims of the present application under 35 U.S.C. § 102(e), is based on U.S. application Serial No. 08/771,217, which was filed on **December 19, 1996** ("the Whayne '217 application"). The present application is a continuation of U.S. application Serial No. 08/961,374, which was itself a continuation-in-part of U.S. application Serial No. 08/769,856 ("the Yang '856 application"). The '856 application was also filed on **December 19, 1996** and issued as U.S. Patent No. 6,332,880 ("the Yang '880 patent").<sup>5</sup>

Turning to the rejection under 35 U.S.C. § 102(e), the drawings and "detailed description of the preferred embodiments" portion of the specification were essentially identical in the Whayne '217 application and the Yang '856 application. For example, as shown in the chart below, the portions of the Whayne '279 patent identified in the Final Office Action and Advisory Action are identically present in the Yang '880 patent.

<b>The Whayne '279 Patent</b>	<b>The Yang '880 Patent</b>
Figures 1, 18-24 and 53.	Figures 1, 18-24 and 53.
The specification at column 16, lines 16-18.	The specification at column 16, lines 4-6.

Thus, the merits of the rejection notwithstanding, to the extent that the Whayne '279 patent anticipates claims 10-12, 15-23 and 27-37 under 35 U.S.C. § 102(e), claims 10-12, 15-23 and 27-37 are entitled to priority to the December 19, 1996 filing date of the Yang '856 application under 35 U.S.C. § 120. Given that the effective filing dates of claims 10-12, 15-23 and 27-37 and the Whayne '279 patent would then be the same,

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<sup>5</sup> The Yang '880 patent is of record in the present application.

the Whayne '279 patent is not prior art with respect to claims 10-12, 15-23 and 27-37 under 35 U.S.C. § 102(e).<sup>6</sup> The rejection of claims 10-12, 15-23 and 27-37 under 35 U.S.C. § 102(e) is, therefore, improper and must be reversed.

## IX. CONCLUDING REMARKS

As applicant has shown above, the rejections of claims 10-13 and 15-37 are improper and should be reversed.

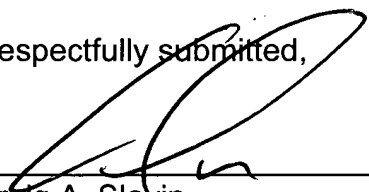
The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

2/14/03

Date

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Respectfully submitted,

  
\_\_\_\_\_  
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<sup>6</sup> 35 U.S.C. § 102(e) requires that the claimed invention be "described in a patent granted on an application for patent by another filed in the United States **before** the invention thereof by the applicant."

## Appendix



10. A catheter assembly, comprising:
  - a handle including a handle body and a strain relief element;
  - an elongate catheter body defining a distal portion, a proximal portion associated with the handle, and a size and flexibility suitable for insertion into a human body; and
  - a control element defining a distal portion operably connected to the distal portion of the catheter body and a proximal portion extending along the exterior surface of the catheter body and secured to the strain relief element.
11. A catheter assembly as claimed in claim 10, wherein the control element comprises a pull wire.
12. A catheter assembly as claimed in claim 10, wherein the control element defines a distal end, the catheter body defines a distal end, and the distal end of the control element is associated with the distal end of the catheter body.
13. A catheter assembly as claimed in claim 10, wherein the control element is secured to the strain relief element by a substantially tubular member which surrounds respective portions of the strain relief element and the control element.
14. A catheter assembly as claimed in claim 13, wherein the substantially tubular member comprises heat shrink tubing.
15. A catheter assembly as claimed in claim 10, further comprising:
  - a sheath surrounding at least respective portions of the catheter body and control element.

16. A catheter assembly as claimed in claim 10, further comprising:  
a physiological treatment element carried by the distal portion of the elongate catheter body.

17. A catheter assembly as claimed in claim 16, wherein the physiological treatment element comprises a diagnostic element.

18. A catheter assembly as claimed in claim 16, wherein the physiological treatment element comprises a therapeutic element.

19. A catheter assembly as claimed in claim 16, wherein the physiological treatment element comprises an electrode element.

20. A catheter assembly as claimed in claim 19, wherein the electrode element comprises a porous electrode element.

21. A catheter assembly as claimed in claim 19, wherein the electrode element comprises a flexible electrode element.

22. A catheter assembly, comprising:  
a handle including a handle body;  
an elongate catheter body defining a distal portion, a proximal portion associated with the handle, and a size and flexibility suitable for insertion into a human body;

a control element defining a distal portion operably connected to the distal portion of the catheter body and a proximal portion extending along the exterior surface of the catheter body; and

an apparatus, located in spaced relation to the handle body, adapted to secure the proximal portion of the control element in predetermined relation to the catheter body.



23. A catheter assembly as claimed in claim 22, wherein the handle includes a strain relief element associated with the handle body and the apparatus includes the strain relief element.

24. A catheter assembly as claimed in claim 23, wherein the apparatus further includes a device that secures the proximal portion of the control element to the strain relief element.

25. A catheter assembly as claimed in claim 24, wherein the device comprises an anchoring element.

26. A catheter assembly as claimed in claim 25, wherein the anchoring element comprises a tube.

27. A catheter assembly as claimed in claim 22, wherein the apparatus covers a region of the proximal portion of the control element and a region of the proximal portion of the catheter body.

28. A catheter assembly as claimed in claim 22, wherein the apparatus comprises an anchoring element that secures the proximal portion of the control element to the proximal portion of the catheter body.

29. A catheter assembly as claimed in claim 28, wherein the anchoring element comprises a tube.

30. A catheter assembly as claimed in claim 22, wherein the control element comprises a pull wire.

31. A catheter assembly as claimed in claim 22, further comprising:  
a sheath surrounding at least respective portions of the catheter body and control element.

32. A catheter assembly as claimed in claim 22, further comprising:  
a physiological treatment element carried by the distal portion of the elongate catheter body.

33. A catheter assembly as claimed in claim 32, wherein the physiological treatment element comprises a diagnostic element.

34. A catheter assembly as claimed in claim 32, wherein the physiological treatment element comprises a therapeutic element.

35. A catheter assembly as claimed in claim 32, wherein the physiological treatment element comprises an electrode element.

36. A catheter assembly as claimed in claim 35, wherein the electrode element comprises a porous electrode element.

37. A catheter assembly as claimed in claim 35, wherein the electrode element comprises a flexible electrode element.